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The PADHOC Device is a Better Guide to the Actual Incapacity Suffered by Claudicants than the Gold Standard Constant Load Treadmill Test

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Background. *The Constant Load Treadmill Test (CLTT) is currently the primary method used to measure walking impairment in patients with peripheral vascular disease. The aim of this study was to compare the CLTT and PADHOC device as assessments of walking impairment.*
Methods. *55 patients with intermittent claudication underwent a CLTT and a Double Physiological Walking Test (DPWT) using the PADHOC device. Health-related quality of life was measured using the Short Form 36 and the Claudication Scale.*
Results. *The initial claudication and maximum walking distance from the first part of the DPWT showed the best correlation with domains of pain and physical function.*
Conclusions. *The DPWT is more representative of the functional incapacity experienced by patients with intermittent claudication. We believe that the PADHOC is a suitable alternative to the CLTT in the assessment of this patient group.*

Keywords: PADHOC; Intermittent claudication; Constant load treadmill test.

Introduction

Intermittent claudication is the most common presenting symptom of patients with peripheral arterial disease. The measurement of walking distances is an integral part of the initial assessment of the claudicant. The estimation of walking distance is inaccurate.[1] The Constant Load Treadmill Test (CLTT) is felt to be the "gold standard" laboratory determinant of walking distances in claudicants, but it is associated with a number of shortcomings.[2] A high proportion of claudicants are unable to undertake or complete a CLTT, usually due to concomitant comorbidity.[3–4] Differing treadmill protocols have limited the potential of comparison between studies and the use of the treadmill itself is limited to predominately a laboratory-based setting.[5–7] The PADHOC (Peripheral Arterial Disease Holter Control Device) device and the associated Double Physiological Walking Test (DPWT) is a novel way of determining a claudicants walking distance.[3,8] The aim of this study was to determine whether the PADHOC was a superior measure of functional incapacity in claudicants, when compared to a CLTT.

Patients and Methods

Ethical committee approval was given for this study and informed consent obtained from each patient enrolled. Fifty-five patients with intermittent claudication were recruited into this prospective study over a year-long period. All the patients recruited to this study had been invited to take part in a prospective study being undertaken by the department determining the effect of different treatment modalities in intermittent claudication. Inclusion criteria were the ability to undergo both a CLTT and the DPWT using the PADHOC device. Patients with severe exercise limiting disease were excluded (i.e. severe ischaemic heart disease, chronic obstructive pulmonary disease and osteoarthritis). Patients with critical ischaemia and tissue loss, as defined by the Transatlantic Inter-Society Consensus (TASC) document, were also excluded from the study.[9] Each patient underwent both a CLTT and the DPWT. Both tests were performed on the same day with a one-hour rest period between

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them. The CLTT consisted of a treadmill test at a speed of 2.5 km/h at an incline of 10° for a maximum of 5 min. Pre and post-exercise ankle brachial pressure indices (ABPI's) were determined, as were the initial claudication distance (ICD_t) and the maximum walking distance (MWD_t). Disease severity was thus determined using SVS/ISCVS criteria.[10]

The PADHOC device

This device consists of a main unit worn by the patient, on a belt, which contains a removable computer card that records the data (Fig. 1). It is connected to two ultrasound sensors (a transmitter sensor and a receiver sensor), each fixed over the patient's medial malleoli by ankle straps, and to a control module held in the patient's hand. The test is performed indoors on level ground. As the patient commences walking, they press the green button. At the onset of claudication pain, the patient presses the yellow button and the red button is then pressed when the patient can walk no further. The patient then rests, standing for one minute, and the test is then repeated. For each test ICD, MWD and speed are calculated and the whole test is known as the Double Physiological Walking Test (DPWT). The belt pack receives and processes the signal and displays the results on a LED screen. The device has a number of advantages.

Fig. 1. The main unit worn by the patient.

Principle of the PADHOC device

The measurement principle of the PADHOC device is based upon ultrasound telemetry. Walking distance is calculated by the continuous measurement of the distance between the patients medial malleoli. The transmitting sensor sends an ultrasound signal to the receiver sensor 64 times a second. The main unit measures the time taken for the signal to travel from one sensor to the other. The distance between the medial malleoli is calculated by multiplying this time by the sound propagation speed. All measurements of this distance are plotted as a sinusoidal curve. Each oscillation on the curve corresponds to one step. Maximum variations correspond to the moment when both feet touch the ground. Therefore, each maximum variation represents the actual walking distance travelled during one step. The sum of all the maximum intermalleolar distances is used to calculate the walking distance. This allows the parameters ICD, MWD and walking speed to be measured for both parts of the DPWT.

Principle of the double physiological walking tests with the PADHOC system

During the walking test, the pain that causes the patient to stop is thought to occur at the same time as the decrease in ankle pressure (Fig. 2).[8] The speed at which the ankle pressure recovers to its initial pre-exercise value varies according to the functional state of the collateral circulation. After the patient has rested, standing, for one minute the pain subsides but the ankle pressure may still remain at a lower value than that prior to the initial walking period. It would seem reasonable that the longer time it takes for the ankle pressure to recover to its original value, the shorter a second walking test carried out under the same conditions will be. Using this principle, disease severity can be measured by determining distance ratios for both ICD and MWD between the first and second walking tests (ICD_2/ICD_1 and MWD_2/MWD_1 respectively), with lower values representing more severe disease.

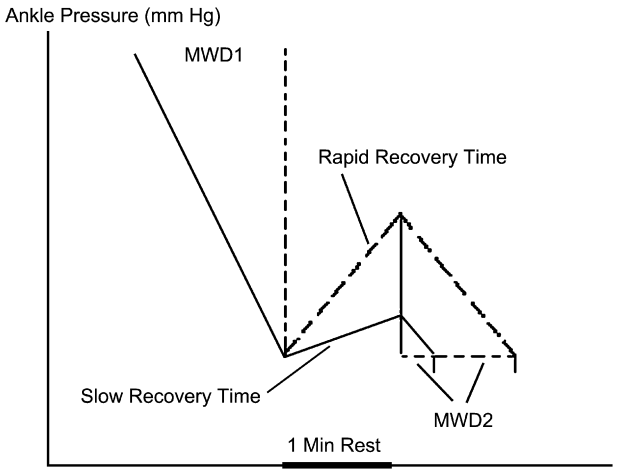

Fig. 2. Representation of the principle behind the Double Physiological Walking Test.

The Short-Form 36

Each patient also completed the generic Short Form 36 (SF 36) QoL instrument. This was undertaken on the same day as the two walking assessments. The SF 36 is a well-validated generic QoL tool. It was developed from a previous questionnaire − the Medical Outcomes Study General Health Survey Instrument − with the aim of providing a short yet comprehensive and psychometrically sound instrument.[11] It contains 36 questions covering eight health domains. Questions for each domain are coded, summed and transformed on a scale of 0 (worst possible health) to 100 (best possible health). The SF 36 has been validated in population studies.[12,13] Furthermore, it has been suggested that the SF 36 is the most appropriate generic QoL tool to be used in patients with lower limb ischaemia.[14] The health domains for physical function and pain (Physical Function (PF), Role Physical (RP) and Bodily Pain (BP)) were used to reflect the patients functional incapacity.

The Claudication Scale (CLAU-S)

The CLAU-S is a disease-specific instrument, which has been developed in Germany.[15] It consists of 47 items covering the 5 health dimensions of Daily Living, Pain, Social Life, Disease-Specific Anxiety and Mood. For all domains, the score is calculated as the mean of the completed items of each domain and the results transformed so that for all domains 0 represents the worse and 100 the best possible QoL.

The health domains of both questionnaires can be conveniently grouped into physical function, bodily pain, social function and psychological function. The health domains for physical function and pain from the two QoL tools have been used as markers of functional incapacity in this study.

Statistical Analysis

All values are expressed as median (interquartile range) except where specified. Spearman rank correlation coefficient (r_s) was used to determine correlation between walking distances and QoL scores. Significance was determined as a p value < 0.050. Statistical analysis was performed using Analyse-it software (Leeds, U.K.)

Results

Demographics

Of the 55 patients recruited, 30 were men and the overall median age was 69 years (range 48−85 years). Seven patients had mild claudication, 29 moderate claudication and 19 severe claudication as determined by SVS/ISCVS criteria.[9] Median pre exercise ABPI was 0.73 (0.58−0.82) and median post exercise ABPI was 0.53 (0.36−0.71). Of the 55 patients, 7 were diabetic, 32 had a positive smoking history, 23 were known to be hypertensive and 28 known to be hypercholesterolaemic.

Walking parameters for the CLTT and the DPWT

All patients were able to complete the CLTT and the DPWT. The median ICD_t was 30.5 metres (21−50 metres) and the median MWD_t was 60 metres (40−101 metres). The median ICD_1 and MWD_1 were 113.5 metres (68.75−165.5 metres) and 234 metres (154.5−475.5 metres) respectively. The median ICD_2 and MWD_2 were 33 metres (4−90 metres) and 127 metres (81−265 metres) respectively. The median ICD ratio (ICD_2/ICD_1) from the DPWT was 0.35 (0.04−0.78) and the median MWD ratio (MWD_2/MWD_1) from the DPWT was 0.57 (0.42−0.81).

Walking parameters and QoL domains (Table 1)

The ICD_t had lower correlation coefficients for the domains of pain and physical function compared to the ICD_1. The MWD_t had lower correlation coefficients for the domains of pain and physical function compared to the MWD_1 apart from the CLAU-S domain of Daily Living. The ICD_2 showed a weak correlation with the health domains of Physical Function and Role

Table 1. Comparison between initial claudication distances (ICD) for the treadmill test and the first part of the DPWT with the QoL health domains. Values are Spearman Rank Correlation Coefficient (r_s)

	QoL health domain	ABPI Pre	ABPI Post	Treadmill ICD	Treadmill MWD	PADHOC ICD_1	PADHOC MWD_1	PADHOC ICD_2	PADHOC MWD_2
Physical activity	CLAU-S Daily Living	0.06	−0.11	0.50*	0.53*	0.58*	0.46*	0.18	0.32†
	SF-36 Physical Function	0.18	0.02	0.60*	0.66*	0.63*	0.68*	0.31†	0.63*
	SF-36 Role Physical	0.12	−0.04	0.32†	0.35†	0.49*	0.63*	0.26†	0.43*
Pain	CLAU-S Pain	0.23	0.08	0.33†	0.30†	0.39*	0.32†	0.34*	0.31†
	SF-36 Bodily Pain	0.06	0.02	0.39*	0.39*	0.46*	0.51*	0.04	0.32†

* $p < 0.01$.
† $p < 0.05$.

Physical (SF 36) and the domain of Pain (CLAU-S). There was no significant correlation between the domains of Daily Living (CLAU-S) and Bodily Pain (SF 36) and the ICD_2. The MWD_2 has a significant correlation with all of the health domains analysed. All walking distances obtained from both the CLTT and the DPWT excluding the ICD_2 significantly correlated with all QoL domains for Pain and Physical function. The ICD_2 failed to correlate significantly with either the CLAU-S Daily Living or the SF-36 Bodily Pain domains. Disease severity as measured from both the DPWT (ICD_2/ICD_1.and MWD_2/MWD_1) or the CLTT (ISCVS/SVS criteria) did not correlate with any of the markers of functional incapacity (data not shown).

Discussion

The assessment of intermittent claudication is multifaceted. Assessment of the patient's co-morbidity will determine the relative fitness for any form of intervention with parallel risk factor profiling and subsequent modification being obligatory. The assessment of a patients walking distance plays a role in determining disease severity as well as facilitating the assessment of the overall incapacity experienced by the claudicant. Given that claudication distances are poorly estimated, an accurate assessment of walking status is needed for studies.[1] The overall assessment of the claudicant has recently been supplemented by the introduction of quality of life analysis. Health, as defined by the World Health Organisation, is not only "the absence of infirmity but also a state of physical, social and mental well being".[16] The design of the majority of QoL tools is largely based upon this definition. The SF 36 is a well-validated generic QoL questionnaire that has been routinely used in a number of claudication studies.[7,14,17,18] It is simple and easy to understand and is relatively quick to complete. Indeed it has been suggested that the SF 36 should be looked upon as the "gold standard" generic QoL tool for the patients with peripheral arterial disease.[14] Functional incapacity itself is a difficult concept to accurately measure. The Walking Impairment Questionnaire (WIQ) has been used in claudicant groups to measure walking ability.[19] The questionnaire addresses the issues of walking distance, walking speed and stair-climbing capacity. It correlates well with objective walking ability in patients with and without peripheral arterial disease.[19] However, overall physical function is not limited solely to walking ability and indeed in the claudicant population it is likely that perceived pain will also affect physical function. Some studies have used more specific markers of physical function, such as the Leisure Time Physical Activity Questionnaire (LTPAQ) and the Stanford 7-day Physical Activity Recall Questionnaire (PARQ) but, their limited use restricts the opportunity for comparison between studies.[20,21] The SF 36 addresses a wide variety of issues with regard to physical function. The SF 36 not only determines the effect of disease on walking but also addresses other activities including shopping, bathing and dressing. It also asks the patient to determine the effect of their physical health on their work and daily activities.

For many years, the CLTT has been the gold standard method of determining walking distances in patients with intermittent claudication. Despite this widespread use, there are a number of associated deficiencies with the CLTT. The rigidity of the test parameters with regard to speed and incline, has not only limited the number of claudicants able to undertake a CLTT but results in an artificial setting with regard to the intensity of the work undertaken by the claudicant. Due to this, it has been suggested that the test does not reflect the actual functional incapacity experienced by the claudicant on a day-to-day basis. The graded treadmill test has similar associated problems again due to the artificial test environment. Comparison

between studies is limited due to the use of variable study protocols.[5–7] A number of other methods have been developed to try to improve upon the assessment of walking ability.[2,22] The 6 min walking test, although, probably more representative of daily walking ability is limited by the rigid test criteria that need to be met for the results to be reliable with the subsequent chance of inter-observer variability.

The PADHOC was designed to overcome all these problems. It is safe and simple to use and the results obtained are not affected by observer variation. It allows the claudicant to walk at their normal pace therefore mimicking the conditions they experience on a daily basis. Claudicants who are unable to undergo a CLTT are therefore able to have an assessment of their walking ability.[4] The DPWT using the PADHOC has been shown to correlate well with a CLTT.[4] It had been shown to accurately reflect improvements following therapeutic interventions although as yet its ability to discriminate between arterial claudication and other causes of leg pain has not been determined.[23] The DPWT allows the measurement of ankle pressures prior to and after exercise if so required. A recent study of eighty patients had shown that in older patients with intermittent claudication, objective measures which include the ankle-brachial index, time to maximum claudication pain on a graded exercise test, and a 6-minute floor-walking distance correlated with a self-reported, disease-specific and generic quality of life.[24]

This study further supports the use of the PADHOC as an alternative measure of walking ability. The PADHOC shows superior correlation with markers of physical function and pain for both the ICD_1 and MWD_1 when compared to the treadmill walking distances. The only exception to this is the health domain of Daily Living (CLAU-S), which shows superior correlation with the MWD_t than MWD_1. The MWD_2 of the DPWT also shows strong correlation with the markers of physical function and pain although the correlation coefficients are all lower than those obtained for the MWD_1.

The lack of correlation with the ICD_2 is in keeping with other studies of the PADHOC suggesting that its only role in the assessment of the claudicant is in the determination of disease severity using the ratio of ICD_2 to ICD_1. Although the walking distance ratios fail to correlate with functional impairment as determined by QoL analysis, previous work has shown that diseases severity as determined by the DPWT correlates with SVS/ISCVS criteria.[4] This would suggest that it is not solely the walking distances in a claudicant population that affects their daily functional incapacity. Correlation measures the strength of a relation between two variables and not the agreement between them. However, although both tests are measuring walking distances, the tests differ in the degree of stress placed upon the patients. One would expect different walking distances for each test in the same patients. The use of correlation is therefore used to determine which walking test more closely reflects a marker of functional incapacity (QoL tools). The difference in correlation coefficients with regard to ICD are small and therefore it may well be that there is really no clinical difference in functional incapacity if one was to consider solely the ICD. However, the differences in correlation coefficients when considering the MWD of the two walking tests and the QOL scores are larger with regard to Role Physical domain and to a lesser extent the Bodily Pain domain (MWD_1 only) and therefore could be considered to more likely reflect a clinical difference.

Overall, the results would suggest that the PADHOC device and the subsequent DPWT is more representative of the functional incapacity experienced by the claudicant. We suggest that the PADHOC is a worthwhile alternative to the CLTT for the assessment of the walking ability of all claudicants in clinical trials used in combination with a QoL tool.

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